

01-15-03

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: THOMAS et al.

Serial No.: 09/497,957

Group Art Unit: 1644

Filed: February 4, 2000

Examiner: DECLOUX, A.

For: PLASMIDS COMPRISING NUCLEIC  
ACIDS FROM THE HEREDITARY  
HEMOCHROMATOSIS GENE

Attorney Docket No.: 8907-087-999

~~PT#11~~  
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a.  A list of all patents, publications, applications, or other information submitted for consideration by the office.
- 1b. A legible copy of :
  - Each U.S. patent application publication and U.S. and foreign patent, other than copies of AA-EQ, previously submitted and of reference in Serial No. 08/834,497, filed on April 4, 1997--See Section 6 of this IDS;
  - Each publication or that portion which caused it to be listed on the PTO-1449, other than copies of AA-EQ, previously submitted and of reference in Serial No. 08/834,497, filed on April 4, 1997--See Section 6 of this IDS;
  - For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
  - all other information or portion which caused it to be listed on the PTO-1449.

- 1c.  An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
- 1d.  Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2.  This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - Before the mailing of the first Office action on the merits;
  - Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3.  This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.
  - 3a.  The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
  - 3b.  The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
    - enclosed
    - to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150 (Order No. 8907-087-999).
4.  This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:
  - enclosed.
  - to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5.  Certification Statement (*applicable if Item 3a or Item 4 is checked*)
  - 5a.  In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

5b.  In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

6.  This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

6a.  A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

6b.  The above-identified application is a continuation of U.S. Patent Application Serial No. 08/834,497, filed on April 4, 1997. References listed herein as AA-EQ are of record in U.S. Patent Application Serial No. 08/834,497. Therefore, pursuant to 37 C.F.R. §1.98(d), copies of these references are not submitted herewith. However, if the Examiner would prefer, copies of these references will be made available to the Examiner upon request.

6c.  Copies of the references listed on Form PTO-1449 as references ER-GS were not previously cited in prior application Serial No. 08/834,497, filed on April 4, 1997 , and are provided herewith for consideration.

7.  This is a Supplemental Information Disclosure Statement.

7a.  This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on \_\_\_. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on \_\_\_.

7b.  This Supplemental Information Disclosure Statement is timely filed within one (1) month of a PTO Notice under 37 C.F.R. §1.97(i).

8.  In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

8a.  satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.

8b.  set forth in the application.

8c.  enclosed as an attachment hereto.

9.  The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150 (order no. 8907-087-999).

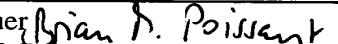
10.  No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

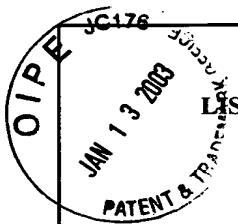
Respectfully submitted,

Date January 13, 2003

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Birgit Millauer,   
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## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.	APPLICATION NO.
8907-087-999	09/497,957
APPLICANT	
THOMAS et al.	
FILING DATE	GROUP
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U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	ER	4,511,503	Apr. 1985	Olson et al.			
	ES	5,582,979	Dec. 1996	Weber			
	ET	5,719,125	Feb. 1998	Suzuki et al.			
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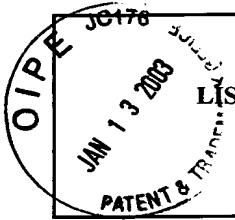
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLAS S	TRANSLATION	
							YES	NO
	EV	WO 96/06583	Mar. 1996	WO				

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EZ	Balan, V., et al., "Screening fro Hemochromatosis: A Cost-Effectiveness Study Based on 12,258 Patients," Gastroenterology (1994) 107:453-459 (0016/5085/94).
FA	Beaucage, S.L., et al., "Deoxynucleoside Phosphoramidites-A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters (1981) 22(20):1859-1862 (0040-4039/81).
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FC	Benton, W.D., et al., "Screening λgt Recombinant Clones by Hybridization to Single Plaques in situ," Science (1977) 196:180-182 (National Institutes of Health).
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FF	Broach, J.R., et al., "Transformation in Yeast: Development of a Hybrid Cloning Vector and Isolation of the CAN1 Gene," Gene (1979) 8:121-133 (National Institutes of Health).
FG	Campbell, A.M., "Monoclonal Antibody Technology," Elsevier Science Publishers (1985) Chapter 1 pp. 1-32 (ISBN 0-444-80592-3).

EXAMINER	DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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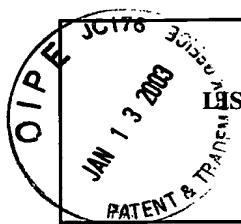
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FK	Cornall, R.J., et al., "The Generation of a Library of PCR-Analyzed Microsatellite Variants for Genetic Mapping of the Mouse Genome," Genomics (1991) 10:874-881 (0888-7543/91).
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FR	Gubler, U., et al., "A Simple and Very Efficient Method for Generating cDNA Libraries," Gene (1983) 25:263-269 (0888-1119/83).
FS	Herskowitz, I., et al., "The Lysis-Lysogeny Decision of Phage $\lambda$ : Explicit Programming and Responsiveness," Ann. Rev. Genet. (1980) 14:399-445 (0066-4197/80).
FT	Hinnen, A., et al., "Transformation of Yeast," Proc. Natl. Acad. Sci. USA (1978) 75(4):1929-1933 (National Science Foundation).
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FW	Levy-Lahad, E., et al., "Candidate Gene for the Chromosome 1 Familial Alzheimer's Disease Locus," Science (1995) 269:973-977 (National Institute on Aging for the Alzheimer's Diseases Research Center).
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GH	Queen, C., et al., "Cell-Type Specific Regulation of a κ Immunoglobulin Gene by Promoter and Enhancer Elements," Immunol. Rev. (1986) 89:49-68 (National Institutes of Health).
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GJ	Schneider, I., "Cell Lines Derived From Late Embryonic Stages of <i>Drosophila Melanogaster</i> ," J. Embryol. Exp. Morph. (1972) 27(2):353-365 (Walter Reed Army Institute of Research).
GK	Smith, T.F., et al., "Comparison of Biosequences," Adv. Appl. Math. (1981) 2:482-489 (0196-8858/81).
GL	Sprague, J., et al., "Expression of a Recombinant DNA Gene Coding for the Vesicular Stomatitis Virus Nucleocapsid Protein," J. Virol. (1983) 45(2):773-781 (0022-538X/83).
GM	Strathmann, M., et al., "Transposon-Facilitated DNA Sequencing," Proc. Natl. Acad. Sci. USA (1991) 88:1247-1250 (U.S. Public Health Service Program).
GN	Summers, K.M., et al., "HLA Determinants in an Australian Population of Hemochromatosis Patients and Their Families," Am. J. Hum. Genet. (1989) 45:41-48 (0002-9297/89).
GO	Taylor, M.R., et al., "Cloning and Sequence Analysis of Human Butyrophilin Reveals a Potential Receptor Function," Biochimica et Biophysica Acta (1996) 1306:1-4 (0167-4781/96).
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GQ	Walker, G.T., et al., "Isothermal in vitro Amplification of DNA by a Restriction Enzyme/DNA Polymerase System," Proc. Natl. Acad. Sci. USA (1992) 89:392-396 (Becton Dickinson Research Center).

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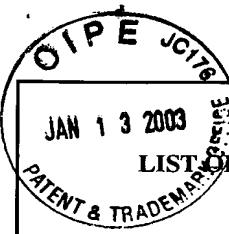


<b>LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>		ATTY. DOCKET NO. 8907-087-999	APPLICATION NO. 09/497,957
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	GS	Yu, C-E., et al., "Positional Cloning of the Werner's Syndrome Gene," <i>Science</i> (1996) 272:258-262 (National Institute on Aging).

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	AB	4,434,156	Feb. 1984	Trowbridge			
	AC	4,666,927	May. 1987	Hider et al.			
	AD	4,683,202	Jul. 1987	Mullis			
	AE	4,711,845	Dec. 1987	Gelfand et al.			
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	AJ	5,185,368	Feb. 1993	Peter et al.			
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							YES	NO
	AQ	CA 2115221	Aug. 1994	CA				
	AR	CA 2115222	Aug. 1994	CA				
	AS	CA 2115224	Aug. 1994	CA				
	AT	EP 0 315 434	May. 1989	EP				
	AU	EP 0 346 281	Dec. 1989	EP			X	Abstr.
	AV	DE 208 609	Apr. 1984	DE				X

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	BL	Bjorkman, P.J., et al., "Structure, Function, and Diversity of Class I Major Histocompatibility Complex Molecules," Annu. Rev. Biochem. (1990) 59:253-288 (0066-4154/90).
	BM	Calandro, L.M., et al., "Characterization of a Recombinant That Locates the Hereditary Hemochromatosis Gene Telomeric to HLA-F," Hum. Genet. (1995) 96:339-342 (Kaiser Foundation Research Institute).
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	BO	Capecci, M.R., "Altering the Genome by Homologous Recombination," Science (1989) 244:1288-1292 (Univ. of Utah Medical Center).

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BW	Edwards, C.Q., et al., "The Locus for Hereditary Hemochromatosis Maps Between HLA-A and HLA-B," Cytogenet. Cell Genet. (1985) 40:620 (Univ. of Utah Medical Center).
BX	Edwards, C.Q., et al., "Screening for Hemochromatosis," New Engl. J. Med. (1993) 328(22):1616-1619 (Univ. of Utah College of Medicine).
BY	El Kahloun, A., et al., "Localization of Seven New Genes Around the HLA-A Locus," Hum. Molec. Genet. (1992) 2(1):55-60 (Institut National de la Sante et de la Recherche Medicale).
BZ	Fahy, E., et al., "Self-Sustained Sequence Replication (3SR): An Isothermal Transcription-Based Amplification System Alternative to PCR," PCR Methods and Applications (1991) 1:25-33 (1054-9803/91).
CA	Feder, J.N., et al., "A Novel MHC Class I-Like Gene is Mutated in Patients With Hereditary Haemochromatosis," Nature Genet. (1996) 13:399-408 (Mercator Genetics).
CB	Finch, C.A., "Hemochromatosis—Treatment is Easy, Diagnosis Hard," Western J. Med. (1990) 153(3):323-325 (Univ. of Washington School of Medicine).
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CE	Fullan, A., et al., "A Polymorphic Dinucleotide Repeat at the Human HLA-F Locus," Hum. Mol. Genet. (1994) 3(12):2266 (Mercator Genetics).
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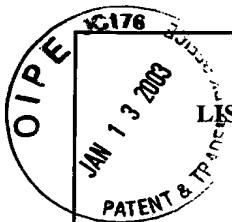


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CG	Gnirke, A., et al., "Physical Calibration of Yeast Artificial Chromosome Contig Maps by RecA-Assisted Restriction Endonuclease (RARE) Cleavage," Genomics (1994) 24:199-210 (0888-7543/94).
CH	Goei, V.L., et al., "Isolation of Novel Non-HLA Gene Fragments From the Hemochromatosis Region (6p21.3) by cDNA Hybridization Selection," Am. J. Hum. Genet. (1994) 54:244-251 (0002-9297/94).
CI	Gruen, J.R., et al., "Physical and Genetic Mapping of the Telomeric Major Histocompatibility Complex Region in Man and Relevance to the Primary Hemochromatosis Gene (HFE)," Genomics (1992) 14:232-240 (0378-7543/92).
CJ	Gyapay, G., et al., "The 1993-1994 Genethon Human Genetic Linkage Map," Nature Genetics (1994) 7:246-339 (Assoc. Francais conte les Myopathies).
CK	Halliday, J.W., "Hemochromatosis and Iron Needs," Nutr. Rev. (1998) 56(2):S30-S37 (Queensland Institute of Medical Research).
CL	Harlow, E., et al., "Antibodies: A Laboratory Manual," Cold Spring Harbor Laboratory (1988) Chapter 5 pp. 75-81 (ISBN 0-87969-314-2).
CM	Hashimoto, K., et al., "Identification of a Mouse Homolog for the Human Hereditary Haemochromatosis Candidate Gene," Biochem. Biophys. Res. Comm. (1997) 230:35-39 (0006-291X/97).
CN	Jakobovits, A., et al., "Production of Antigen-Specific Human Antibodies from Mice Engineered with Human Heavy and Light Chain YACs <sup>a</sup> ", Ann. N.Y. Acad. Sci. (1995) 764:525-535 (Cell Genesys, Inc.).
CO	Jazwinska, E.C., et al., "Localization of the Hemochromatosis Gene Close to D6S105," Am. J. Hum. Genet. (1993) 53:347-352 (0002-9297/93).
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CQ	Jazwinska, E.C., et al., "Where Does the Gene for Hemochromatosis Lie in Relation to HLA-A?," Hepatology (1994) 19:1050-1051 (Queensland Institute of Medical Research). <b>This reference was incorrectly listed in the 08/834,497 PTO-1449 as authored by Gasparini, P., et al.</b>
CR	Jazwinska, E.C., et al., "Hemochromatosis and "HLA-H": Definite!," Hepatology (1997) 25(2):495-496 (Queensland Institute of Medical Research).
CS	Jouet, M.M.H., et al., "Isolation of YAC Clones Containing Class I HLA Genes Which Map in the Vicinity of the Hereditary Haemochromatosis Gene," J. Med. Genet. (1991) 28(8):572 (St. Mary's Hospital, Manchester).
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CU	Koller, B.H., et al., "Normal Development of Mice Deficient in $\beta_2$ M, MHC Class I Proteins, and CD8 <sup>+</sup> T Cells," Science (1990) 248:1227-1230 (National Institutes of Health).
CV	Kramer, M.F., et al., "The Polymerase Chain Reaction," Current Protocols in Molecular Biology (1993) Chapter 15 pp. 15.0.1-15.1.14 (ISBN 0-471-30661-4).
CW	Landegren, U., et al., "A Ligase-Mediated Gene Detection Technique," Science (1988) 241(4869):1077-1080 (0036-8075/88).

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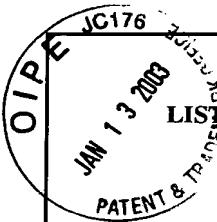
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CY	Lin, A.Y., et al., "Expression of T Cell Antigen Receptor Heterodimers in a Lipid-Linked Form," Science (1990) 249:677-679 (Stanford Univ. School of Medicine).
CZ	Lipinski, M., et al., "Idiopathic Hemochromatosis: Linkage with HLA," Tissue Antigens (1978) 11:471-474 (Hopital Saint-Louis, Paris).
DA	Maskos, U., et al., "A Novel Method for the Parallel Analysis of Multiple Mutations in Multiple Samples," Nucl. Acids Res. (1993) 21(9):2269-2270 (Univ. of Oxford).
DB	Miyazaki, J.I., et al., "Intracellular Transport Blockade Caused by Disruption of the Disulfide Bridge in the Third External Domain of Major Histocompatibility Complex Class I Antigen," Proc. Natl. Acad. Sci. USA (1986) 83:757-761 (National Institutes of Health).
DC	Morgan, J.G., et al., "The Selective Isolation of Novel cDNAs Encoded by the Regions Surrounding the Human Interleukin 4 and 5 Genes," Nucl. Acids Res. (1992) 20(19):5173-5179 (National Center for Human Genome Research).
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DH	Nickerson, D.A., et al., "Automated DNA Diagnostics Using an ELISA-Based Oligonucleotide Ligation Assay," Proc. Natl. Acad. Sci. USA (1990) 87:8923-8927 (Whittier Foundation).
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DN	Patterson, M., et al., "Molecular Characterization of Cell Cycle Gene CDC7 From <i>Saccharomyces Cerevisiae</i> ," Mol. Cell Biol. (1986) 6(5):1590-1598 (0270-7306/86).

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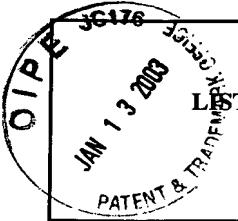
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	DP	Raha-Chowdhury, R., et al., "New Polymorphic Microsatellite Markers Place the Haemochromatosis Gene Telomeric to D6S105," Hum. Mol. Genet. (1995) 4(10):1869-1874 (Univ. of Wales College of Medicine).
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	DS	Roth, M.P., et al., "The Human Myelin Oligodendrocyte Glycoprotein (MOG) Gene: Complete Nucleotide Sequence and Structural Characterization," (1995) Genomics 28:241-250 (0888-7543/95).
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	DU	Saiki, R.K., et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," Science (1988) 239:487-491 (Cetus Corp.).
	DV	Saiki, R.K., et al., "Genetic Analysis of Amplified DNA With Immobilized Sequence-Specific Oligonucleotide Probes," Proc. Natl. Acad. Sci. USA (1989) 86:6230-6234 (Cetus Corp.).
	DW	Salter, R.D., "Intracellular Transport of Class I HLA Molecules is Affected by Polymorphic Residues in the Binding Groove," Immunogenetics (1994) 39:266-271 (American Cancer Society).
	DX	Schild, H., et al., "The Nature of Major Histocompatibility Complex Recognition by $\gamma\delta$ T Cells," Cell (1994) 76:29-37 (German Cancer Research Center).
	DY	Sevier, E.D., "Monoclonal Antibodies in Clinical Immunology," Clin. Chem. (1981) 27(11):1797-1806 (Hybritech, Inc.).
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	EA	Simon, M., et al., "A Study of 609 HLA Haplotypes Marking for the Hemochromatosis Gene: (1) Mapping of the Gene Near the HLA-A Locus and Characters Required to Define a Heterozygous Population and (2) Hypothesis Concerning the Underlying Cause of Hemochromatosis-HLA Association," Am. J. Hum. Genet. (1987) 41:89-105 (0002-9297/87).
	EB	Sood, A. K., et al., "Isolation and Partial Nucleotide Sequence of a cDNA Clone for Human Histocompatibility Antigen HLA-B by Use of an Oligodeoxynucleotide Primer," Proc. Natl. Acad. Sci. USA (1981) 78(1):616-620 (National Institutes of Health).
	EC	Stone, C., et al., "Isolation of CA Dinucleotide Repeats Close to D6S105; Linkage Disequilibrium With Haemochromatosis," Hum. Molec. Genet. (1994) 3(11):2043-2046 (Queensland Institute of Medical Research).
	ED	Summers, K.M., et al., "Fine Mapping of a Human Chromosome 6 Ferritin Heavy Chain Pseudogene: Relevance to Haemochromatosis," Hum. Genet. (1991) 88:175-178 (Queensland Institute of Medical Research).
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EG	Totaro, A., et al., "New Polymorphisms and Markers in the HLA Class I Region: Relevance to Hereditary Hemochromatosis (HFE)," Hum. Genet. (1995) 95:429-434 (Italian Ministry of Health).
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EI	Wagner, R., et al., "Mutation Detection Using Immobilized Mismatch Binding Protein (MutS)," Nucl. Acids Res. (1995) 23(19):3944-3948 (Genecheck Inc.).
EJ	Wallace, R.B., et al., "Hybridization of Synthetic Oligodeoxyribonucleotides to $\Phi\chi$ 174 DNA: The Effect of Single Base Pair Mismatch," Nucl. Acids Res. (1979) 6(11):3543-3557 (City of Hope National Medical Center).
EK	Weber, J.L., et al., "Dinucleotide Repeat Polymorphism at the D6S105 Locus," Nucl. Acids Res. (1991) 19(4):968 (National Institutes of Health).
EL	Wettstein, D.A., et al., "Expression of a Class II Major Histocompatibility Complex (MHC) Heterodimer in a Lipid-Linked Form With Enhanced Peptide/Soluble MHC Complex Formation at Low pH," J. Exp. Med. (1991) 174:219-228 (0022-1007/91).
EM	Worwood, M., et al., "Alleles at D6S265 and D6S105 Define a Haemochromatosis-Specific Genotype," Brit. J. Hematol. (1994) 86:863-866 (Univ. of Wales College of Medicine).
EN	Wu, D.Y., et al., "The Ligation Amplification Reaction (LAR)-Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," Genomics (1989) 4:560-569 (0888-7543/89).
EO	Youil, R., et al., "Screening for Mutations by Enzyme Mismatch Cleavage With T4 Endonuclease VII," Proc. Natl. Acad. Sci. USA (1995) 92:87-91 (National Health and Medical Research Council of Australia).
EP	Zijlstra, M., et al., " $\beta$ 2-Microglobulin Deficient Mice Lack CD4 $^+$ 8 $^+$ Cytolytic T Cells," Nature (1990) 344:742-746 (Cancer Research Institute).
EQ	Zinkernagel, R.M., et al., "MHC-Restricted Cytotoxic T Cells: Studies on the Biological Role of Polymorphic Major Transplantation Antigens Determining T-Cell Restriction-Specificity, Function, and Responsiveness," Adv. In Immunol. (1979) 27:51-177 (ISBN 0-12-022427-5).

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